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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,212	04/05/2001	Ying-Fei Wei	1488.1280006	3523
28730	7590	06/14/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			O HARA, EILEEN B	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 06/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/826,212

Applicant(s)

WEI ET AL.

Examiner

Eileen O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 221-282 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 221-282 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 221-282 are pending in the instant application. Claims 117-220 have been canceled and claims 221-282 have been added as requested by Applicant in the Paper filed March 22, 2004.

Withdrawn Objections and Rejections

2. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. New claims 221-282 are rejected under 35 U.S.C. 102(e) as being anticipated by Ashkenazi et al., US Patent Application Publication No.2002/0161202, effective filing date June 18, 1997 (08/878,168), for reasons of record in the previous Office Action mailed October 20, 2003, and below.

Claims 221-282 encompass isolated polypeptide of SEQ ID NO: 2 (encoded by the cDNA clone contained in ATCC Deposit No. 97788), produced by a eukaryotic host cell, further comprising a heterologous polypeptide which may be a human

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immunoglobulin Fc region, and composition comprising the polypeptide and a carrier, and are thus drawn to the same invention as original claims 117-220.

On pages 12-18 of the response, Applicants traverse the priority determination discussed on pages 3-4 of the previous office action mailed Oct. 20, 2003. Applicants assert that the manner of making and using an inventions disclosed in a specification (or as here the priority document) must be accepted by the PTO “unless there is reason to doubt the objective truth of the statements contained therein.”, that definite proof of an inventions utility is not required under 35 U.S.C. § 101, and cite *In re Marzocchi*, the Utility Examination Guidelines, M.P.E.P., *In re Brana*, *Brenner* and *Juicy Whip, Inc. v. Orange Bang Inc.* Applicants on page 14 assert that a *prima facie* showing of no specific and substantial utility “must establish that it is more likely than not that a person skilled in the art would not consider that any utility asserted by the applicant would be specific and substantial.”, and that the Examiner has not made the required showing that even one, much less all, of the utilities disclosed for TNFR-5 in the first priority document would be unbelievable in light of the teachings of the document and the knowledge of one skilled in the art. On pages 15-18, Applicants assert that the first priority document discloses several statements that specifically set forth Applicants’ assertion of the biological role for the soluble extracellular domain of TNFR-5, and that Applicants clearly understood that the receptor of SEQ ID NO: 2 does not possess an intracellular signaling domain, and that at the time of the first priority document Applicants had clearly established a specific and substantial utility for the soluble extracellular form of TNFR-5, as an antagonist of TNFR activity, to antagonize TNFR mediated signaling with competing with the cell surface TNFR for binding the TNFR-family ligands, for example

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to inhibit tumor necrosis induced by TNF-family ligands. Applicants further assert on pages 17-18 that standard cell-based assays were available to assess the cellular responses such as apoptosis, and could be routinely performed by one of ordinary skill in the art, and that without knowing the ligand which binds TNFR-5, one of ordinary skill could perform screening assays using the approximately 10 known TNF-family ligands to screen for cellular responses.

Applicants' arguments have been fully considered but are not deemed persuasive. The numerous asserted utilities for the polypeptide and encoding nucleic acid in provisional document 60/035,496, including use as hybridization probes, in chromosome and gene mapping, in the generation of anti-sense RNA and DNA, to identify molecules that bind to TNFR-5, to make "knock-out" mice or other animals, in gene therapy, as molecular weight markers, therapeutic agents, and for the production of antibodies. The utilities that pertain solely to nucleic acids (e.g. hybridization, chromosome and gene mapping, anti-sense) would not convey to the encoded protein. With respect to the remaining utilities, none of these asserted utilities is specific for the disclosed TNFR-5 protein, as each of the aforementioned utilities could be asserted for any naturally occurring protein, and further, as none of the asserted utilities requires any feature or activity that is specific to the disclosed TNFR-5.

Applicants' arguments that the TNFR-5 receptor could be used as an antagonist or to discover what ligands it binds to, have been fully considered but are not deemed persuasive. Further experimentation to investigate the properties of what is claimed is not a specific and substantial utility. The receptors in the TNF receptor family are involved in myriad biological pathways and activities and disorders. Although homology

to the TNF receptor family and expression provides some evidence that the claimed protein is a member of the TNF receptor superfamily, it is not predictable what the function of the protein of the instant invention is from this information. Whereas a broad class of enzyme such as the ligases have a general utility in such an application as ligation of DNA for cloning purposes and which is essentially applicable to all of the members of that class, the class of proteins known as TNF receptors do not have a common practical utility which is based upon a property common to all of the members of that class. Members of this superfamily bind to a large variety of different ligands, mediate different signals, are expressed in different cell types and modulate different physiological processes, and are involved in different diseases and/or disorders, and it is not predictable what the specific physiological function of a TNF type receptor is based on homology to other members of this family (Wallach, D. (2000) TNF ligand and TNF/NGF receptor families. In: Cytokine Reference (Joost J. Oppenheim and Marc Feldmann editors in chief, Academic Press (London), 377-411). Though the protein of the instant invention may be classified as a member of the TNF receptor superfamily, this does not automatically confer a specific and substantial utility to the protein, since there is diversity in the activities and biological functions of these receptors. There was no ligand known to bind the TNFR-5 protein, and the "antagonistic" activities upon ligand binding were also not known for this protein in provisional 60/035,496. Although assays could be used at the time to determine the activities of the receptor, the use of an orphan receptor to discover its ligand or properties does not constitute a specific, substantial utility. In *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct., 1966), a process of producing a novel compound that was structurally analogous to other compounds which were

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known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are “useful” to the chemical arts when this term is given its broadest interpretation.

However, the court held that this broad interpretation was not the intended definition of “useful” as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed “real world” utility. As stated in *Brenner v. Manson*, “ a patent is not a hunting liscense. It is not a reward for the search, but compensation for its successful conclusion.”

Therefore, provisional document 60/035,496 did not support a specific and substantial utility for the protein, and the priority determination and rejection are maintained.

It is believed that all pertinent arguments have been answered.

Conclusion

4. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

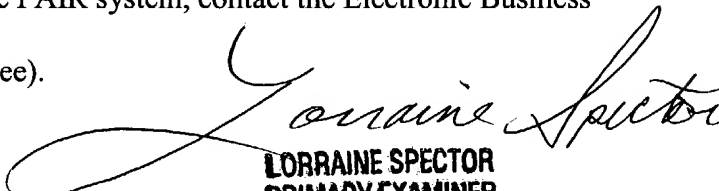
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (571) 272-0887.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.ispto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.



**LORRAINE SPECTOR
PRIMARY EXAMINER**

Patent Examiner